K021470

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## 510(k) Summary of Safety and Effectiveness

NOV 1 4 2002

Date:
November 12, 2002

Submitter:
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:
Lisa Lee Michels
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
Phone: (262) 293-1609
Fax: (414) 918-8203

Device: Trade Name:
SEER Light Compact Digital Holter Recorder or (SEER Light)

Common/Usual Name:
Digital Ambulatory Monitor

Classification Names:
21 CFR 870.2800 Electrocardiograph, Ambulatory (without Analysis) MWJ

Predicate Devices:
K001317 Aria Digital Holter Recorder®

Device Description:
The SEER Light Compact Digital Holter Recorder is designed to acquire ambulatory 2 or 3 channels of ECG signal from the chest surface for no longer than 24 hours. The device stores the acquired ECG data in its on-board 32 megabytes of flash memory. Additionally, the SEER Light controller downloads patient demographic information into the SEER Light recorder and checks the signal quality of the ECG data at hookup time via isolated, infra-red communications. At the end of the recording the SEER Light controller is connected to the SEER Light recorder by cable and the stored ECG data is transferred to it and onto a standard compact flash memory card.

Intended Use:
The intended use of the SEER Light Compact Digital Holter Recorder is to acquire ambulatory 2 or 3 channels of ECG signal from the chest surface of pediatric or adult patients for no longer than 24 hours. The device stores this data along with patient demographic information to on board flash memory. It does not perform any analysis on the ECG data.

The SEER Light Compact Digital Holter Recorder is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Technology:
The proposed SEER Light employs the same technology as the predicate device.

Test Summary:

The SEER Light complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the SEER Light Compact Digital Holter Recorder is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2002

GE Medical Systems Information Technologies
c/o Ms. Lisa Lee Michels
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K021470
Trade Name: SEER Light Compact Digital Holter Recorder and Controller
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: August 23, 2002
Received: August 26, 2002

Dear Ms. Michels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021470

Device Name: SEER Light Compact Digital Holter Recorder

Indications For Use:

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The SEER Light Compact Digital Holter Recorder is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021470
Elias Mallis

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)